UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA

Akiko Shoshido, Robin Stroebel and Iris Mataro **Plaintiffs,** **Vs.** **Steve Galella, D.D.S., OrthoMatrix Corp., Inc., also d/b/a Facial Beauty Institute, and d/b/a as OrthoLogic and John's Dental Laboratory, Inc.** **Defendants.**	**CASE NO:** 2:21-CV-00438

Plaintiffs' Complaint

Plaintiffs Akiko Shoshido, Robin Stroebel, and Iris Mataro, by and through their undersigned counsel, by way of Complaint against John's Dental Laboratory, Inc. ("John's Dental"), Steve Gallella, D.D.S., and OrthoMatrix Corp, Inc., also d/b/a as Facial Beauty Institute ("FBI"), and d/b/a as OrthoLogic hereby allege as follows:

PARTIES

1. Plaintiff Akiko Shoshido is an individual and, at the time of the filing of the Complaint, is a citizen of the United Kingdom, with an address at 47 Elmwood Road, London, England, United Kingdom SE24 9NS. Her claims arise from the laws of Indiana and the laws of the United Kingdom and/or the European Union.

2. Plaintiff Robin Stroebel is an individual and at the time of the filing of the Complaint a citizen of Canada, with an address at 2544 Farmcrest Avenue K9L 1H7, Peterborough, Ontario, Canada. Her claims arise from the laws of Indiana and Ontario, Canada.

3. Plaintiff Iris Mataro is an individual and at the time of the filing of the Complaint a citizen of the Italy, with an address at 45 Boughton Hall Drive, Chester, England, United Kingdom. Her claims arise from the laws of Indiana, and the laws of the United Kingdom and/or the European Union.

4. At the time of the filing of the Complaint, defendant John's Dental was an Indiana Corporation and citizen of Indiana with a principal place of business at 423 South 13th Street in Terre Haute, Indiana, 47807.

5. At the time of the filing of the Complaint, defendant Steve Galella, D.D.S. ("Dr. Galella) was an individual and a citizen of Tennessee residing at 997 Eastwood Terrace, Collierville, Tennessee 38017.

6. At the time of the filing of the Complaint, defendant OrthoMatrix Corp., Inc. ("OrthoMatrix"), d/b/a Facial Beauty Institute ("FBI") and d/b/a as OrthoLogic, was a foreign corporation organized under the laws of the State of Tennessee, and a citizen of Tennessee, with a principal place of business at 875 West Poplar Avenue, Suite 16, Collierville, Tennessee 38017. FBI is a wholly owned division and/or tradename of defendant OrthoMatrix.

JURISDICTION

7. This Court's jurisdiction is based upon diversity of citizenship as set forth in 28 U.S.C. Section 1332 in that at the time of the filing of the Complaint the plaintiffs are citizens of the United Kingdom, Canada and Italy, respectively, and the defendants were citizens of Indiana and Tennessee, respectively.

8. The amount in controversy is in excess of Seventy-Five Thousand Dollars, exclusive of interest and costs (28 U.S.C. § 1332) per plaintiff.

9. This Court has personal jurisdiction over John's Dental because John's Dental is an Indiana Corporation.

10. This Court has personal jurisdiction over the remaining defendants because they regularly conducted business in Indiana with specific connection to the manufacturing, marketing and sale of the device and/or type of device at issue in this Complaint and the claims of plaintiffs. In particular, defendants Galella and OrthoMatrix receive and have received payments from defendant John's Dental related to the manufacture and/or sale of the type of device at issue in this Complaint, including of the exact device at issue in this Complaint.

VENUE

11. Pursuant to 28 U.S.C. 1391, venue is properly laid in this district because a substantial part of the transactions and issues giving rise to plaintiffs' claims occurred in this judicial district.

FACTUAL ALLEGATIONS COMMON TO ALL COUNTS

NATURE OF THE ACTION

12. This is an action for money damages for personal injury suffered by the plaintiffs as the result of the installation of a dental appliance which defendants designed, manufactured and marketed despite no scientific or clinical basis to prove it was either safe or effective.

13. The appliance, known as an "Anterior Growth Guidance Appliance" ("AGGA") was manufactured, designed, and marketed as a proven means of correcting dental, facial and airway abnormalities in lieu of complex jaw surgery for adult patients.

14. Defendants promoted AGGA, taught dentists how it allegedly functioned, and prepared AGGA treatment plans for dentists, claiming that AGGA causes three-dimensional changes in the nasomaxillary complex of adults, including growing/advancing/remodeling the maxilla to move forward horizontally over time by as much or more than 10 mm, through a process of mechanical force and new bone deposition resulting from stimulation of a nerve in the palate, and that it was a reasonable alternative to jaw surgery.

15. Plaintiffs allege that these claims are false, and are contrary to medical science; that instead AGGA works in adults, inter alia, to push the upper teeth out of their housing in the alveolar bone, that it causes no new bone growth or dimensional changes in the nasomaxillary complex of adults (whose nasomaxillary complex, unlike those of children, have topped growing naturally), that it is not a reasonable alternative to jaw surgery for adults, and that it presents a risk of serious and permanent harm for adults.

16. As a result of the fact that, for adults, AGGA as negligently designed and manufactured was not reasonably safe and was unreasonably dangerous, the promotion and teaching of AGGA involving false representations to dentists including plaintiffs' dentists, the creation of a treatment plan utilizing a product that is unreasonably dangerous to adults, the failure to warn plaintiffs and/or their dentists about the actual risks of AGGA to adults, and the installation of AGGA in plaintiffs have caused plaintiffs to sustain significant and permanent damage to their teeth and face, economic loss, disfigurement, embarrassment, loss of enjoyment of life, and physical and mental pain and suffering.

FACTS ALLEGED

HISTORY OF AGGA

17. At all times relevant to the case, Dr. Galella was a general dentist duly licensed by the State of Tennessee and a diplomate of an organization called the International Board of Orthodontics.

18. Prior to January 2010, Dr. Galella designed the dental appliances called AGGA and the Controlled Arch system of brackets and wires ("CAB").

19. Prior to 2010, Dr. Galella founded FBI, and at all times relevant to the Complaint Dr. Galella and FBI shared office space in Tennessee, along with OrthoMatrix.

20. Prior to 2010, FBI became an unincorporated division and/or trade name of OrthoMatrix.

21. At all times relevant to the Complaint, Dr. Galella was an officer of, employed by and working in furtherance of the business of, and/or acted as agent of, FBI and, therefore of OrthoMatrix.

22. At all times relevant to the Complaint, OrthoMatrix, through its division FBI, and Dr. Galella, offered and taught courses to dentists on the use and alleged safety and efficacy of AGGA and CAB.

23. At all times relevant to the Complaint, OrthoMatrix, through its unincorporated division or trade name FBI and/or through another unincorporated division or tradename of OrthoMatrix called OrthoLogic, maintained a program that purported to analyze patients' dental/cranio maxillofacial condition using "radiologists" and "experts" to determine whether said patients were appropriate candidates for AGGA/CAB treatment, and prepare AGGA and CAB treatment plans for such patients with comprehensive instructions that were alleged to be specific and customized for each patient ("the program").

24. At all times relevant to the Complaint, Dr. Galella and OrthoMatrix made certain representations ("the representations") to dentists throughout the world that:

a. AGGA is a device that causes three-dimensional changes in the nasomaxillary complex of adults, including growing/advancing/remodeling the maxilla to move forward horizontally over time by as much or more than 10 mm;

b. AGGA causes these nasomaxillary changes in adults through a process of mechanical force and new bone deposition resulting from stimulation of a nerve in the palate;

c. as the maxilla moves forward, upper teeth move with it, including in adults;

d. by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward, including in adults;

e. the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face, including in adults;

f. AGGA is reasonably safe for installation into dental patients' mouths, including in adults;

g. AGGA can be utilized as a substitute for jaw surgery, including in adults.

25. At all times relevant to the Complaint, Dr. Galella, and OrthoMatrix, made additional representations to dentist throughout the world that, once AGGA causes the desired maxilla and mandible position to be obtained, and AGGA was then removed, CAB could be used to make relatively minor adjustments in order to guide all teeth to their proper positions, as well as to widen the dental arches, including in adults;

26. The representations, made at all times relevant to the Complaint by Dr. Galella, and OrthoMatrix, were made for the purpose of, *inter alia*, causing dentists to promote AGGA and CAB to consumers, including adult consumers in United Kingdom and Ontario, Canada.

27. Neither AGGA nor CAB have ever been submitted to the Federal Drug Administration, or any other government agency, for approval, and they have never been approved by any governmental agency for use in the United States.

28. Dr. Galella, and OrthoMatrix, knew or should have known that, while the representations may have been true in regard to the use of AGGA by children (who are still growing naturally), the representations as to adults were unproven, not supported by medical knowledge or science, and were false and materially misleading, and that:

a. in adults, AGGA is not a device that can cause changes in the nasomaxillary complex of adults;

b. AGGA is not a device that mechanically causes the maxilla of an adult to move forward horizontally over time as much or more than 10 mm;

c. AGGA does not stimulate new bone growth resulting in changes to the nasomaxillary complex of an adult;

d. AGGA does not move the maxilla in an adult; instead, it pushes certain of the upper teeth forward over time within the alveolar bone which is attached to the maxilla;

e. in adults, as AGGA pushes the upper teeth forward, the teeth are pushed out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

f. AGGA does not open an adult user's airway;

g. AGGA is unreasonably dangerous to adult patients in whom it is installed, and is not reasonably safe for use by such patients; and,

h. AGGA is not a substitute for jaw surgery for adults.

29. At all times relevant to the Complaint, John's Dental was in the business of, *inter alia*, manufacturing, selling and putting into the stream of commerce, dental appliances including but not limited to AGGA and CAB, and was bound to anticipate that their products would be, through dental professionals, presented to the general public for their use, including but not limited to use by consumers within each state of the United States, as well as within various European Union countries including Germany.

30. At all times relevant to the Complaint, John's Dental paid a royalty and/or other fee to both OrthoMatrix and to Galella, or an entity controlled by Galella, for every AGGA device manufactured and sold by John's Dental. On information and belief, a similar fee was paid by John's Dental for sales of certain AGGA devices.

PLAINTIFF AKIKO SHISHIDO

31. Prior to April 11, 2018, dentist Dr. David Cook ("Dr. Cook") of London, England, United Kingdom, took a course in the use, safety and efficacy of AGGA.

32. During the aforementioned course, various representations were made to Dr. Cook about the safety and efficacy of AGGA, which representations included those set forth above and which were unproven, not supported by medical knowledge or science, untested by any clinical trial, unsupported by peer-reviewed literature, and which were false and materially misleading

33. On information and belief, the course largely or completely comprised the extent of Dr. Cook's training concerning AGGA and CAB.

34. Prior to April 11, 2018, Ms. Shishido sought treatment from Dr. Cook for, inter alia, condyle compression and dysfunction and pain, and occlusion issues, and Dr. Cook prescribed treatment with an AGGA device for the purpose of addressing such issues, and did install such a device in her on or about April 11, 2018.

35. At no time, during the aforementioned course or otherwise, did anyone warn Dr. Cook or Ms. Shishido that, in regard to adult users, AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was unreasonably dangerous, was not efficacious, and presented a risk of serious and permanent injury to consumers.

36. Prior to April 11, 2018, Dr. Cook consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Ms. Shishido was an appropriate candidate for AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

37. More specifically, prior to April 11, 2018, on information and belief, Dr. Cook submitted a questionnaire and dental records concerning Ms. Shishido to OrthoMatrix's Total Diagnostics internet portal, and thereafter and as a result, OrthoMatrix, through Dr. Galella and others, produced an AGGA/CAB treatment plan for Ms. Shishido ("the Shishido treatment plan") and otherwise represented to Dr. Cook and to Ms. Shishido that AGGA and CAB were appropriate treatments for Ms. Shishido.

38. Prior to April 11, 2018, Dr. Cook, on information and belief in reliance on advice, instruction and guidance provided by OrthoMatrix, and Dr. Galella, submitted information and/or specifications to John's Dental concerning Ms. Shishido and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use by Ms. Shishido.

39. Prior to April 11, 2018, John's Dental did manufacture an AGGA appliance for use by Dr. Cook for installation in Ms. Shishido's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Cook, who was then within the United Kingdom, then a member of the European Union; Germany; John's Dental knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Cook would install it in Ms. Shishido.

40. At the time of sale of the AGGA to Dr. Cook, John's Dental impliedly warranted and represented that the AGGA was fit, capable and suitable for the ordinary purposes for which it was intended, that it was fit for the specific purpose for which it was sold to Dr. Cook, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

41. Ms. Shishido reasonably relied upon the implied warranties of John's Dental, as well as on its skill and judgment.

42. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Cook for use on Ms. Shishido, Dr. Galella did inspect and examine photographs of that AGGA device and of a mold of Ms. Shishido's teeth, knew or should have known that the AGGA device was for an adult's teeth, and pronounced the AGGA fit to be used for Ms. Shishido.

43. At the time of the sale of the AGGA to Dr. Cook, the AGGA was inherently defective by virtue of its design, was not fit for its intended purpose nor for the specific purpose for which it was sold for installation in Ms. Shishido's mouth; it was not of merchantable quality, was not reasonably safe, was unreasonably dangerous and defective, all at the time it left the possession, custody and control of John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles, and in an adult does not change the nasomaxillary complex in three, or any, dimensions, does not stimulate new bone growth, does not move the maxilla forward horizontally by as much or more than 10 mm, does not open a user's airway, is in no way a substitute for jaw surgery in an adult;

b. AGGA is unreasonably dangerous in that, rather than move the maxilla or make any three-dimensional changes in the adult nasomaxillary complex, it pushes the upper teeth forward and, after moving more than a limited amount, out of their safe position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

c. While AGGA may have additional utility for children, the utility of AGGA in an adult is in its moving teeth a limited amount within the bone (a function that can be performed by other, standard orthodontic appliances), is far outweighed by the risks AGGA creates;

d. John's Dental failed to warn Dr. Cook or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

44. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Dr. Cook the AGGA appliance for Ms. Shishido, that appliance was not reasonably safe for use on adults, was not minimally safe for its expected purpose, and was dangerous to the

extent beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses it, with the ordinary knowledge common to such dentists or users.

45. At all times relevant to the Complaint, had Ms. Shishido been warned of the defects and deficiencies of AGGA as described above, she would not have embarked on any course of treatment using AGGA.

46. At all times relevant to the Complaint, had Dr. Cook been warned by any of the defendants of the defects and deficiencies of AGGA as described above then, on information and belief, he would not have embarked on any course of treatment of Ms. Shishido using AGGA.

47. At all times relevant to the Complaint, Ms. Shishido would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

48. Dr. Cook installed the subject AGGA device in Ms. Shishido in April 2018, and it was removed by him in November 2018. Ms. Shishido continued further treatment with Dr. Cook for several years, during which he expressed consistent contentment with Ms. Shishido's condition. In February 2021, Ms. Shishido first discovered that she had been damaged by AGGA.

49. As a result of the installation and use of the AGGA appliances, Ms. Shishido has been caused to suffer significant and permanent injury and damage, including but not limited to: gingival recession, root resorption, bone loss, occlusion, pain, emotional distress, economic loss related to the cost of said worthless and harmful AGGA treatment, prolonged suffering from the conditions for which she originally sought treatment from Dr. Cook as a result of being induced to avoid seeking proper treatment for it; and other injury and damage.

50. Ms. Shishido at all times relevant to the Complaint acted reasonably, and nothing she did or failed to do caused or contributed to cause her injuries.

COUNT I:

Product Liability-Negligence Against Defendant Dr. Galella

51. Plaintiff Akiko Shishido reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

52. Defendant Dr. Galella was negligent in that, *inter alia,* he negligently designed the AGGA devices that was installed in Ms. Shishido, an adult, when he knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to Galella's education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid.

53. Dr. Galella acted with reckless disregard for the safety of others, including Ms. Shishido.

54. As a direct and proximate result of the negligence of Dr. Galella, and his reckless disregard for the safety of others including Ms. Shishido, Ms. Shishido has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Akiko Shishido demands Judgment in an amount in excess of One Hundred Thousand Dollars against defendant Steve Galella, D.D.S., plus interest and costs.

COUNT II:

Negligence Against Defendant Orthomatrix And Defendant Galella

55. Plaintiff Akiko Shishido reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

56. OrthoMatrix was negligent in that, *inter alia,* it, either directly or by or through its division or trade name FBI and/or OrthoLogic, and/or through its officer Galella:

a. negligently produced the Shishido treatment plan for Ms. Shishido's dentist for the installation of an AGGA device on Ms. Shishido, when it knew or should have known that said device was unproven for use by adults, it was neither safe nor efficacious for adults, the principles upon which it allegedly functioned for adults were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous for adults and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Shishido; and,

b. through its officer Galella, approved an AGGA device for use by Ms. Shishido, when Galella knew or should have known by the mold and photographs of Ms. Shishido's teeth as aforesaid that she was an adult, and/or he failed to inquire as to whether Ms. Shishido was indeed an adult; and Galella knew or should have known that said device was unproven for use by adults, it was neither safe nor efficacious for adults, the principles upon which it allegedly functioned for adults were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous for adults and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Shishido.

57. OrthoMatrix and Galella acted with reckless disregard for the safety of others, including Ms. Shishido.

58. As a direct and proximate result of the negligence of OrthoMatrix and Dr. Galella, and their reckless disregard for the safety of others including Ms. Shishido, Ms. Shishido has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Akiko Shishido demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Orthomatrix Corp., Inc., and defendant Steve Galella, D.D.S., plus interest and costs.

COUNT III:

Product Liability-Breach Of Warranties Against Defendant John's Dental

59. Plaintiff Akiko Shishido reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

60. At the time that the AGGA device that was sold to Ms. Shishido's dentist last left the possession, custody or control of John's Dental, the device was inherently defective by virtue of its design, was not fit for their intended purpose nor for the specific purpose for which it was sold for installation in Ms. Shishido's mouth, was not of merchantable quality, was not reasonably or minimally safe, was unreasonably dangerous and defective, and the utility of the device in moving teeth through adult bone as done by orthodontic appliances was outweighed by the risk of substantial risk of harm, all at the time it left the possession, custody and control of John's Dental, for reasons that were described above, in regard to its use by adults.

61. The defective nature of the subject AGGA device includes its lack of warnings, at the time it last left the possession, custody and control of defendant John's Dental, in that it failed to warn purchasers of AGGA, or anyone else:

a. of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

b. that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla;

c. that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth.

d. that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

e. if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

62. When used for the purpose for which it was intended, AGGA has limited utility for adults and presents a risk of serious and permanent injury to adults when used as intended by the designer, manufacturer and seller to make dimensional changes in the nasomaxillary complex, all as aforesaid.

63. As a result of the foregoing, John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the aforesaid AGGA device sold to Ms. Shishido's dentist and installed in Ms. Shishido's mouth.

64. Ms. Shishido relied on the aforementioned implied warranties in agreeing to the installation of the AGGA devices.

65. As a direct and proximate result of those breaches of implied warranties, separately and together, Ms. Shishido has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Akiko Shishido demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT IV:

Product Liability- Negligence Against Defendant John's Dental

66. Plaintiff Akiko Shishido reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

67. At the time the subject AGGA device was sold by John's Dental to Ms. Shishido's dentist, John's Dental knew or should have known that the device, for use in adults, was not reasonably safe, was negligently designed and in a condition not reasonably contemplated by Ms. Shishido, the ultimate user, including for the reasons that the function for which it was designed was not possible to achieve and was in contravention of principles of physiology and anatomy, and the devices carried substantial risk of serious injury for adults, and that it lacked necessary warnings as above.

68. At the time the AGGA device was sold by John's Dental to Ms. Shishido's dentist, the product posed a substantial likelihood of harm to Ms. Shishido or any other adult user and was unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency when used in adults, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare

out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Ms. Shishido as a result of the use of the product.

69. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to adult users.

70. The negligent and defective design of the AGGA devices installed in Ms. Shishido's mouth was the sole and/or substantial cause and/or factor in bringing about her injuries or damages.

WHEREFORE, plaintiff Akiko Shishido demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

PLAINTIFF ROBIN STROEBEL

71. Plaintiff Robin Stroebel reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

72. Prior to January 27, 2020, dentist Dr. Andrea Stevens ("Dr. Stevens") of Kanata, Ontario, Canada, took a course in the use, safety and efficacy of AGGA.

73. During the aforementioned course, various representations were made to Dr. Stevens about the safety and efficacy of AGGA, which representations included those set forth above and which were unproven, not supported by medical knowledge or science, untested by any clinical trial, unsupported by peer-reviewed literature, and which were false and materially misleading

74. On information and belief, the course largely or completely comprised the extent of Dr. Stevens' training concerning AGGA and CAB.

75. Prior to January 27, 2020, Ms. Stroebel sought treatment from Dr. Stevens for, inter alia, displaced joint discs, facial pain, occlusion issues and migraines, and Dr. Stevens prescribed

treatment with an AGGA device for the purpose of addressing such issues and did install such a device in her on or about January 27, 2020.

76. At no time during the aforementioned course or otherwise did anyone ever warn Dr. Stevens or Ms. Stroebel that, in regard to adult users, AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was unreasonably dangerous, was not efficacious, and presented a risk of serious and permanent injury to consumers.

77. Prior to January 27, 2020, Dr. Stevens consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Ms. Stroebel was an appropriate candidate for AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

78. More specifically, prior to January 27, 2020, on information and belief, Dr. Stevens submitted a questionnaire and dental records concerning Ms. Stroebel to OrthoMatrix's Total Diagnostics internet portal, and thereafter and as a result, OrthoMatrix, through Dr. Galella and others, produced an AGGA/CAB treatment plan for Ms. Stroebel ("the Stroebel treatment plan") and otherwise represented to Dr. Stevens and to Ms. Stroebel that AGGA and CAB were appropriate treatments for Ms. Stroebel.

79. Prior to January 27, 2020, Dr. Stevens, on information and belief in reliance on advice, instruction and guidance provided by OrthoMatrix, and Dr. Galella, submitted information and/or specifications to John's Dental concerning Ms. Stroebel and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use by Ms. Stroebel.

80. Prior to January 27, 2020, John's Dental did manufacture an AGGA appliance for use by Dr. Stevens for installation in Ms. Stroebel's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Stevens, who was then within Ontario, Canada; John's Dental

knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Stevens would install it in Ms. Stroebel.

81. At the time of sale of the AGGA to Dr. Stevens, John's Dental impliedly warranted and represented that the AGGA was fit, capable and suitable for the ordinary purposes for which it was intended, that it was fit for the specific purpose for which it was sold to Dr. Stevens, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

82. Ms. Stroebel reasonably relied upon the implied warranties of John's Dental, as well as on its skill and judgment.

83. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Stevens for use on Ms. Stroebel, Dr. Galella did inspect and examine photographs of that AGGA device and of a mold of Ms. Stroebel's teeth, knew or should have known that the AGGA device was for an adult's teeth, and pronounced the AGGA fit to be used for Ms. Stroebel.

84. At the time of the sale of the AGGA to Dr. Stevens, the AGGA was inherently defective by virtue of its design, was not fit for its intended purpose nor for the specific purpose for which it was sold for installation in Ms. Stroebel's mouth; it was not of merchantable quality, was not reasonably safe, was unreasonably dangerous and defective, all at the time it left the possession, custody and control of John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles, and in an adult does not change the nasomaxillary complex in three, or any, dimensions, does not stimulate new bone growth, does not move the maxilla forward horizontally by as much or more than 10 mm, does not open a user's airway, is in no way a substitute for jaw surgery in an adult;

b. AGGA is unreasonably dangerous in that, rather than move the maxilla or make any three-dimensional changes in the adult nasomaxillary complex, it pushes the upper teeth forward and, after moving more than a limited amount, out of their safe position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

c. While AGGA may have additional utility for children, the utility of AGGA in an adult is in its moving teeth a limited amount within the bone (a function that can be performed by other, standard orthodontic appliances), is far outweighed by the risks AGGA creates;

d. John's Dental failed to warn Dr. Stevens or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

85. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Dr. Stevens the AGGA appliance for Ms. Stroebel, that appliance was not reasonably safe for use on adults, was not minimally safe for its expected purpose, and was dangerous to the extent beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses it, with the ordinary knowledge common to such dentists or users.

86. At all times relevant to the Complaint, had Ms. Stroebel been warned of the defects and deficiencies of AGGA as described above, she would not have embarked on any course of treatment using AGGA.

87. At all times relevant to the Complaint, had Dr. Stevens been warned by any of the defendants of the defects and deficiencies of AGGA as described above then, on information and belief, she would not have embarked on any course of treatment of Ms. Stroebel using AGGA.

88. At all times relevant to the Complaint, Ms. Stroebel would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

89. By October 2020, Ms. Stroebel became aware that the AGGA device that had been installed in her was causing severe and permanent injury, and she had the device removed.

90. As a result of the installation and use of the AGGA appliances, Ms. Stroebel has been caused to suffer significant and permanent injury and damage, including but not limited to: gingival recession, root resorption, bone loss, occlusion, pain, emotional distress, economic loss related to the cost of said worthless and harmful AGGA treatment, prolonged suffering from the conditions for which she originally sought treatment from Dr. Stevens as a result of being induced to avoid seeking proper treatment for it; and other injury and damage.

91. Ms. Stroebel at all times relevant to the Complaint acted reasonably, and nothing she did or failed to do caused or contributed to cause her injuries.

COUNT V:

Product Liability-Negligence Against Defendant Dr. Galella

92. Plaintiff Robin Stroebel reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

93. Defendant Dr. Galella was negligent in that, *inter alia,* he negligently designed the AGGA devices that was installed in Ms. Stroebel, an adult, when he knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to Galella's education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid.

94. Dr. Galella acted with reckless disregard for the safety of others, including Ms. Stroebel.

95. As a direct and proximate result of the negligence of Dr. Galella, and his reckless disregard for the safety of others including Ms. Stroebel, Ms. Stroebel has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Robin Stroebel demands Judgment in an amount in excess of One Hundred Thousand Dollars against defendant Steve Galella, D.D.S., plus interest and costs.

COUNT VI

Negligence Against Defendant Orthomatrix And Defendant Galella

96. Plaintiff Robin Stroebel reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

97. OrthoMatrix was negligent in that, *inter alia,* it, either directly or by or through its division or trade name FBI and/or OrthoLogic, and/or through its officer Galella:

a. negligently produced the Stroebel treatment plan for Ms. Stroebel's dentist for the installation of an AGGA device on Ms. Stroebel, when it knew or should have known that said device was unproven for use by adults, it was neither safe nor efficacious for adults, the principles upon which it allegedly functioned for adults were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous for adults and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Stroebel; and,

b. through its officer Galella, approved an AGGA device for use by Ms. Stroebel, when Galella knew or should have known by the mold and photographs of Ms. Stroebel's teeth as aforesaid that she was an adult, and/or he failed to inquire as to whether Ms. Stroebel was indeed an adult; and Galella knew or should have known that said device was unproven for use by adults, it was neither safe nor efficacious for adults, the principles

upon which it allegedly functioned for adults were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous for adults and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Stroebel.

98. OrthoMatrix and Galella acted with reckless disregard for the safety of others, including Ms. Stroebel.

99. As a direct and proximate result of the negligence of OrthoMatrix and Dr. Galella, and their reckless disregard for the safety of others including Ms. Stroebel, Ms. Stroebel has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Robin Stroebel demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Orthomatrix Corp., Inc., and defendant Steve Galella, D.D.S., plus interest and costs.

COUNT VII:

Product Liability-Breach Of Warranties Against Defendant John's Dental

100. Plaintiff Robin Stroebel reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

101. At the time that the AGGA device that was sold to Ms. Stroebel's dentist last left the possession, custody or control of John's Dental, the device was inherently defective by virtue of its design, was not fit for their intended purpose nor for the specific purpose for which it was sold for installation in Ms. Stroebel's mouth, was not of merchantable quality, was not reasonably or minimally safe, minimally safe, its utility in its moving teeth a limited amount within the bone was outweighed by the risks it creates, and was unreasonably dangerous and defective, all at the time it left the possession, custody and control of John's Dental, for reasons that were described above, in regard to its use by adults.

102. The defective nature of the subject AGGA device includes its lack of warnings, at the time it last left the possession, custody and control of defendant John's Dental, in that it failed to warn purchasers of AGGA, or anyone else:

a. of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

b. that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla;

c. that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth.

d. that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

e. if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

103. When used for the purpose for which it was intended, AGGA has limited utility for adults and presents a risk of serious and permanent injury to adults when used as intended by the

designer, manufacturer and seller to make dimensional changes in the nasomaxillary complex, all as aforesaid.

104. As a result of the foregoing, John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the aforesaid AGGA device sold to Ms. Stroebel's dentist and installed in Ms. Stroebel's mouth.

105. Ms. Stroebel relied on the aforementioned implied warranties in agreeing to the installation of the AGGA devices.

106. As a direct and proximate result of those breaches of implied warranties, separately and together, Ms. Stroebel has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Robin Stroebel demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT VIII

Product Liability- Negligence Against Defendant John's Dental

107. Plaintiff Robin Stroebel reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

108. At the time the subject AGGA device was sold by John's Dental to Ms. Stroebel's dentist, John's Dental knew or should have known that the device, for use in adults, was not reasonably safe, was negligently designed and in a condition not reasonably contemplated by Ms. Stroebel, the ultimate user, including for the reasons that the function for which it was designed was not possible to achieve and was in contravention of principles of physiology and anatomy,

and the devices carried substantial risk of serious injury for adults, and that it lacked necessary warnings as above.

109. At the time the AGGA device was sold by John's Dental to Ms. Stroebel' dentist, the product posed a substantial likelihood of harm to Ms. Stroebel or any other adult user and was unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency when used in adults, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Ms. Stroebel as a result of the use of the product.

110. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to adult users.

111. The negligent and defective design of the AGGA devices installed in Ms. Stroebel's mouth was the sole and/or substantial cause and/or factor in bringing about her injuries or damages.

WHEREFORE, plaintiff Robin Stroebel demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT IX:

Ontario Sale of Goods Act ("SGA") and Ontario Consumer Protection Act ("CPA") Against Defendant John's Dental)

112. Plaintiff Robin Stroebel reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

113. Ontario Sale of Goods Act ("SGA") and Ontario Consumer Protection Act ("CPA") make unlawful any deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in Canada.

114. John's Dental has engaged in consumer-oriented conduct that is materially misleading, in that said defendant has, in the course of marketing AGGA to adult consumers (including Canadian consumers) directly, and to dentists (including Canadian dentists) for the purpose of enticing consumers (including Canadian consumers) to use AGGA, represented falsely that:

a. AGGA is a device that causes three-dimensional changes in the nasomaxillary complex of adults, including growing/advancing/remodeling the maxilla to move forward horizontally over time by as much or more than 10 mm;

b. AGGA causes these nasomaxillary changes in adults through a process of mechanical force and new bone deposition resulting from stimulation of a nerve in the palate;

c. as the maxilla moves forward, upper teeth move with it, including in adults;

d. by adhering bite plates to the lower molars, the lower jaw moves forward as the upper jaw moves forward, including in adults;

e. the movement of the jaws has the effect of opening the airway, and moving the jaws into a position more natural for the user's face, including in adults;

f. AGGA is reasonably safe for installation into dental patients' mouths, including in adults;

g. AGGA can be utilized as a substitute for jaw surgery, including in adults.

115. These false representations are material in that they go to the essence of the function of AGGA as claimed by John's Dental, and their falsity means that the product is essentially useless for adults.

116. AGGA is unreasonably dangerous as designed and manufactured, and can cause substantial and permanent damage, as set forth above.

117. As a direct and proximate result of the material misrepresentations, Ms. Stroebel allowed AGGA to be installed in his mouth, and as a result suffered serious and permanent injury as described above.

118. This conduct of John's Dental has affected and will continue to affect not just Ms. Stroebel but also adult consumers at large within Canada who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

119. This conduct of John's Dental has also affected and will continue to affect Canadian dentists who, based on those misrepresentations, will utilize AGGA on adult Canadian consumers and thereby visit substantial and permanent injury on such consumers who seek to reconfigure their jaws for a host of reasons including resolving issues of insufficient airway, severe dental crowding, disfigurement of chin or jawline or other reasons.

120. John's Dental, through its material misrepresentations, has violated SGA and CPA, thereby causing Ms. Stroebel severe and permanent injury and damage as described above.

WHEREFORE, plaintiff Robin Stroebel demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus treble damages, attorneys' fees, interest and costs.

PLAINTIFF IRIS MATARORI

121. Plaintiff Iris Mataro reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

122. Prior to July 2019, dentist Dr. Cook took a course in the use, safety and efficacy of AGGA.

123. During the aforementioned course, various representations were made to Dr. Cook about the safety and efficacy of AGGA, which representations included those set forth above and which were unproven, not supported by medical knowledge or science, untested by any clinical trial, unsupported by peer-reviewed literature, and which were false and materially misleading

124. On information and belief, the course largely or completely comprised the extent of Dr. Stevens' training concerning AGGA and CAB.

125. Prior to July 2019, Ms. Mataro sought treatment from Dr. Cook for, inter alia, occlusion issues and a narrow upper maxilla, and Dr. Cook prescribed treatment with an AGGA device for the purpose of addressing such issues, and did install such a device in her on or about July 2019.

126. At no time during any course or otherwise, did anyone ever warn Dr. Cook or Ms. Mataro that, in regard to adult users, AGGA was unproven, was not supported by scientific or medical knowledge, was not reasonably safe, was unreasonably dangerous, was not efficacious, and presented a risk of serious and permanent injury to consumers.

127. Prior to July 2019, Dr. Cook consulted with OrthoMatrix, through Dr. Galella and others, in regard to whether Ms. Mataro was an appropriate candidate for AGGA and CAB, and for the purpose of establishing an AGGA and CAB treatment plan.

128. More specifically, prior to July 2019, on information and belief, Dr. Cook submitted a questionnaire and dental records concerning Ms. Mataro to OrthoMatrix's Total

Diagnostics internet portal, and thereafter and as a result, OrthoMatrix, through Dr. Galella and others, produced an AGGA/CAB treatment plan for Ms. Mataro ("the Mataro treatment plan") and otherwise represented to Dr. Cook and to Ms. Mataro that AGGA and CAB were appropriate treatments for Ms. Mataro.

129. Prior to July 2019, Dr. Cook, on information and belief in reliance on advice, instruction and guidance provided by OrthoMatrix, and Dr. Galella submitted information and/or specifications to John's Dental concerning Ms. Mataro and did place an order for an AGGA appliance to be manufactured by John's Dental for the specific use by Ms. Mataro.

130. Prior to July 2019, John's Dental did manufacture an AGGA appliance for use by Dr. Cook for installation in Ms. Mataro's mouth, did place it in the stream of commerce and did sell that appliance to Dr. Cook, who was then within the United Kingdom, then a member of the European Union; John's Dental knew at the time it was placed into the stream of commerce that it would be installed in a member of the public, and specifically that Dr. Cook would install it in Ms. Mataro.

131. At the time of sale of the AGGA to Dr. Cook, John's Dental impliedly warranted and represented that the AGGA was fit, capable and suitable for the ordinary purposes for which it was intended, that it was fit for the specific purpose for which it was sold to Dr. Cook, that it had no design defects, that it was of merchantable quality, and that it was safe and not unreasonably dangerous.

132. Ms. Mataro reasonably relied upon the implied warranties of John's Dental, as well as on its skill and judgment.

133. Prior to the AGGA being placed into the stream of commerce and sold to Dr. Cook for use on Ms. Mataro, Dr. Galella did inspect and examine photographs of that AGGA device and

of a mold of Ms. Mataro's teeth, knew or should have known that the AGGA device was for an adult's teeth, and pronounced the AGGA fit to be used for Ms. Mataro.

134. At the time of the sale of the AGGA to Dr. Cook, the AGGA was inherently defective by virtue of its design, was not fit for its intended purpose nor for the specific purpose for which it was sold for installation in Ms. Mataro's mouth; it was not of merchantable quality, was not reasonably safe, was unreasonably dangerous and defective, all at the time it left the possession, custody and control of John's Dental, for reasons that include but are not limited to:

a. AGGA as designed, manufactured and sold was not based on valid scientific principles, and in an adult does not change the nasomaxillary complex in three, or any, dimensions, does not stimulate new bone growth, does not move the maxilla forward horizontally by as much or more than 10 mm, does not open a user's airway, is in no way a substitute for jaw surgery in an adult;

b. AGGA is unreasonably dangerous in that, rather than move the maxilla or make any three-dimensional changes in the adult nasomaxillary complex, it pushes the upper teeth forward and, after moving more than a limited amount, out of their safe position within the alveolar bone, causing the teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

c. While AGGA may have additional utility for children, the utility of AGGA in an adult is in its moving teeth a limited amount within the bone (a function that can be performed by other, standard orthodontic appliances), is far outweighed by the risks AGGA creates;

d. John's Dental failed to warn Dr. Cook or anyone else:

(i) of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

(ii) that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move the maxilla;

(iii) that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth;

(iv) that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

(v) if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

135. At the time that John's Dental manufactured, placed into the stream of commerce and sold to Dr. Cook the AGGA appliance for Ms. Mataro, that appliance was not reasonably safe for use on adults, was not minimally safe for its expected purpose, and was dangerous to the extent

beyond which would be contemplated by the ordinary dentist or consumer who purchases or uses it, with the ordinary knowledge common to such dentists or users.

136. At all times relevant to the Complaint, had Ms. Mataro been warned of the defects and deficiencies of AGGA as described above, she would not have embarked on any course of treatment using AGGA.

137. At all times relevant to the Complaint, had Dr. Cook been warned by any of the defendants of the defects and deficiencies of AGGA as described above then, on information and belief, he would not have embarked on any course of treatment of Ms. Mataro using AGGA.

138. At all times relevant to the Complaint, Ms. Mataro would not by exercise of ordinary and reasonable care have discovered the defects and deficiencies of AGGA as described above nor perceived its danger.

139. In December 2019, Ms. Mataro determined that the AGGA device that had been installed was causing her injury, and she had it removed in January 2020.

140. As a result of the installation and use of the AGGA appliances, Ms. Mataro has been caused to suffer significant and permanent injury and damage, including but not limited to: gingival recession, root resorption, bone loss, occlusion, pain, emotional distress, economic loss related to the cost of said worthless and harmful AGGA treatment, prolonged suffering from the conditions for which she originally sought treatment from Dr. Cook as a result of being induced to avoid seeking proper treatment for it; and other injury and damage.

141. Ms. Mataro at all times relevant to the Complaint acted reasonably, and nothing she did or failed to do caused or contributed to cause her injuries.

COUNT X:

Product Liability-Negligence Against Defendant Dr. Galella

142. Plaintiff Iris Mataro reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

143. Defendant Dr. Galella was negligent in that, *inter alia,* he negligently designed the AGGA devices that was installed in Ms. Mataro, an adult, when he knew or should have known that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to Galella's education and training, and to medical science, and was unproven, that AGGA was neither safe nor efficacious in regard to making three-dimensional changes in the adult nasomaxillary complex including forward movement of the maxilla, had limited utility for adults, that it was unreasonably dangerous and that it could and foreseeably would cause the type of injury and damage suffered by plaintiff, all as aforesaid.

144. Dr. Galella acted with reckless disregard for the safety of others, including Ms. Mataro.

145. As a direct and proximate result of the negligence of Dr. Galella, and his reckless disregard for the safety of others including Ms. Mataro, Ms. Mataro has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Iris Mataro demands Judgment in an amount in excess of One Hundred Thousand Dollars against defendant Steve Galella, D.D.S., plus interest and costs.

COUNT XI:

Negligence Against Defendant Orthomatrix And Defendant Galella

146. Plaintiff Iris Mataro reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

147. OrthoMatrix was negligent in that, *inter alia,* it, either directly or by or through its division or trade name FBI and/or OrthoLogic, and/or through its officer Galella:

a. negligently produced the Mataro treatment plan for Ms. Mataro's dentist for the installation of an AGGA device on Ms. Mataro, when it knew or should have known that said device was unproven for use by adults, it was neither safe nor efficacious for adults, the principles upon which it allegedly functioned for adults were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous for adults and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Mataro; and,

b. through its officer Galella, approved an AGGA device for use by Ms. Mataro, when Galella knew or should have known by the mold and photographs of Ms. Mataro's teeth as aforesaid that she was an adult, and/or he failed to inquire as to whether Ms. Mataro was indeed an adult; and Galella knew or should have known that said device was unproven for use by adults, it was neither safe nor efficacious for adults, the principles upon which it allegedly functioned for adults were not supported by and were in contravention of medical knowledge and science, it was unreasonably dangerous for adults and that it could and foreseeably would cause the type of injury and damage suffered by Ms. Mataro.

148. OrthoMatrix and Galella acted with reckless disregard for the safety of others, including Ms. Mataro.

149. As a direct and proximate result of the negligence of OrthoMatrix and Dr. Galella, and their reckless disregard for the safety of others including Ms. Mataro, Ms. Mataro has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Iris Mataro demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant Orthomatrix Corp., Inc., and defendant Steve Galella, D.D.S., plus interest and costs.

COUNT XII:

Product Liability-Breach Of Warranties Against Defendant John's Dental

150. Plaintiff Iris Mataro reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

151. At the time that the AGGA device that was sold to Ms. Mataro's dentist last left the possession, custody or control of John's Dental, the device was inherently defective by virtue of its design, was not fit for their intended purpose nor for the specific purpose for which it was sold for installation in Ms. Mataro's mouth, was not of merchantable quality, was not reasonably or minimally safe, was unreasonably dangerous and defective, and the utility of the device in moving teeth through adult bone as done by orthodontic appliances was outweighed by the risk of substantial risk of harm, all at the time it left the possession, custody and control of John's Dental, for reasons that were described above, in regard to its use by adults.

152. The defective nature of the subject AGGA device includes its lack of warnings, at the time it last left the possession, custody and control of defendant John's Dental, in that it failed to warn purchasers of AGGA, or anyone else:

a. of the limitations of AGGA's utility for adults in that it would move teeth through bone, but could not make three-dimensional changes in the adult nasomaxillary complex including that it cannot move or grow the maxilla, cannot open an adult user's airway, and is in no way a substitute for jaw surgery in an adult;

b. that AGGA should not be used for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla;

c. that using AGGA for the purpose of attempting to make dimensional changes in the adult nasomaxillary complex including attempting to move or grow the maxilla, could result in serious injury including causing teeth to flare out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth.

d. that claims made about AGGA making three-dimensional changes in the nasomaxillary complex of adults were contrary to medical science and unproven; and,

e. if AGGA were used in an adult, the patient should be closely monitored to ensure it was not causing gum recession, root resorption or other injury indicative of excessive movement of teeth through bone.

153. When used for the purpose for which it was intended, AGGA has limited utility for adults and presents a risk of serious and permanent injury to adults when used as intended by the designer, manufacturer and seller to make dimensional changes in the nasomaxillary complex, all as aforesaid.

154. As a result of the foregoing, John's Dental was in breach of the implied warranties of merchantability and fitness for a particular purpose in regard to the aforesaid AGGA device sold to Ms Mataro's dentist and installed in Ms. Mataro's mouth.

155. Ms. Mataro relied on the aforementioned implied warranties in agreeing to the installation of the AGGA devices.

156. As a direct and proximate result of those breaches of implied warranties, separately and together, Ms. Mataro has been substantially and permanently injured and damaged as outlined above.

WHEREFORE, plaintiff Iris Mataro demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

COUNT XIII:

Product Liability- Negligence Against Defendant John's Dental

157. Plaintiff Iris Mataro reaffirms and realleges each of the above paragraphs of the Complaint as if specifically affirmed and alleged herein.

158. At the time the subject AGGA device was sold by John's Dental to Ms. Mataro's dentist, John's Dental knew or should have known that the device, for use in adults, was not reasonably safe, was negligently designed and in a condition not reasonably contemplated by Ms. Mataro, the ultimate user, including for the reasons that the function for which it was designed was not possible to achieve and was in contravention of principles of physiology and anatomy, and the devices carried substantial risk of serious injury for adults, and that it lacked necessary warnings as above.

159. At the time the AGGA device was sold by John's Dental to Ms. Mataro's dentist, the product posed a substantial likelihood of harm to Ms. Mataro or any other adult user and was unreasonably dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it with the ordinary knowledge common to consumers, including because the product's tendency when used in adults, rather than to move the maxilla, is to push the upper teeth forward and out of their proper position within the alveolar bone, causing the teeth to flare

out, damaging the roots of the teeth and gums, and causing damage to and loss of alveolar bone that holds the teeth, all as happened to Ms. Mataro as a result of the use of the product.

160. No reasonable person who knew the risk of harm of using AGGA at the time of manufacture would conclude that the benefit of the product outweighed the risk to adult users.

161. The negligent and defective design of the AGGA devices installed in Ms. Mataro's mouth was the sole and/or substantial cause and/or factor in bringing about her injuries or damages.

WHEREFORE, plaintiff Iris Mataro demands Judgment in an amount in excess of One Hundred Thousand Dollars ($100,000.00) against defendant John's Dental Laboratory, Inc., plus interest and costs.

JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury on all Counts so triable.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, as follows:

1. For compensatory damages in excess of $100,000.00;
2. For punitive damages in an amount to be proven at trial;
3. For attorney's fees and costs of suit incurred herein;
4. For pre-judgment and post-judgment interest as allowed by law; and

5. For such other and further relief as is appropriate under the circumstances.

Respectfully submitted,

s/Alan C. Milstein
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Dated: **November 24, 2021**